UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Lisa Scott, Plaintiff, v. CSL Plasma Inc., formerly ZLB Plasma, Defendant.	Case No. 0:13-cv-02616-JNE-BRT **MEMORANDUM OF LAW IN SUPPORT OF CSL PLASMA INC.'S MOTION FOR SUMMARY JUDGMENT**

I. INTRODUCTION

CSL Plasma asks this Court to dismiss this case with prejudice because:

- This action was untimely commenced under the provisions of the Minnesota Human Rights Act.
- Even if this suit is timely, the business discrimination statute does not apply to donations of plasma.
- Even if the business discrimination statute applied to donations of plasma, Plaintiff has failed to establish the requisite existence of a contract.
- CSL Plasma has established that the action it took with respect to Plaintiff was based on a legitimate business purpose.
- The claims asserted in this action are preempted by federal law and fall within the primary jurisdiction of the Food and Drug Administration.

There is no genuine issue of material fact in this case and Plaintiff has failed to make out an actionable claim under the statute. CSL Plasma is entitled to judgment as a matter of law.

II. STATEMENT OF FACTS

A. Summary of Plaintiff's Claim.

The events leading to this suit began on November 17, 2008 when Plaintiff came to CSL Plasma's Minneapolis collection facility to donate plasma. (Compl. ¶8).[1] Plaintiff Lisa Scott ("Scott" or "Plaintiff") is a male-to-female transgender woman. (Compl. ¶3). She was born male and underwent gender reassignment surgery in 2006. Willing Decl. Ex. A (Scott Tr. 82).[2] She is now "legally female." Ex. A (Scott Tr. 98).

When Scott arrived at CSL Plasma's collection center, she was administered a standard protocol of plasma donation pre-screening, which included various warnings, advisories, questionnaires and tests, and a private, personal interview conducted by a member of CSL Plasma's medical staff, Tina Erickson, a Licensed Practical Nurse (LPN). (Compl. ¶10, 12; Ex. A (Scott Tr. 120)). Scott told Erickson that she was taking hormone medication and that she had undergone gender reassignment surgery. Ex. A (Scott Tr. 112).

In November 2008, CSL Plasma's donor eligibility policies provided for an assessment of a transgender potential donor on a case-by-case basis and stated that a

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1 References to the "Compl." are to Plaintiff's First Amended Complaint, ECF. No. 18.

2 The Declaration of Stephanie J. Willing and exhibits annexed thereto are denoted in this manner: "Ex __." References to deposition testimony transcripts annexed to the Willing Declaration are denoted as "[Last name of deponent] Tr. [page number]."

screener should call corporate medical operations if a transgender individual presented to donate plasma. Ex. C (Simon Tr. 41-47); Ex. J (Nov. 2007 MSR). According to Scott, Erickson left the screening room to consult with a supervisor, who confirmed that Scott was not eligible to donate plasma.[3] Ex. A (Scott Tr. 113-14).[4] Erickson noted in CSL Plasma's donor file regarding Scott that she had been permanently deferred from donating plasma at CSL Plasma "due to sex change operation and hormone replacement medication" and counseled Scott on the reality that CSL Plasma cannot make an independent decision about whether to use the male or female required screening questions. Ex. B (Erickson Tr. 98-99); Ex. I (CSL Donor File).

B. Timeline of Charge and Suit Filing.

On April 20, 2009, Scott filed a charge of discrimination with the EEOC and the Minnesota Department of Human Rights (MDHR), initially alleging discrimination in a public accommodation. Ex. U. She later filed, on October 23, 2009, an amended charge, Ex. V, alleging "business discrimination" under §363A.17, and the MDHR issued a finding of probable cause on the amended charge on June 25, 2010, Ex. W. On July 31,

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3 In its policies effective December 1, 2008, CSL Plasma deferred all transgender potential donors (except when the gender reassignment surgery occurred, essentially, before puberty). Ex. K (Dec. 2008 MSR). There was some question whether Erickson had consulted the December 1, 2008 policy or the November 12, 2007 policy when Scott presented herself for a donation on November 17, 2008. However, based Scott's deposition testimony, it appears that Erickson followed the November 12, 2007 policy.

4 Scott also alleges that Erickson said "You can't give plasma…we can't take plasma from your type." (Compl. ¶13.) Erickson denies making that statement. Ex. B (Erickson Tr. 106). This factual dispute is not material because Scott's allegation only involves CSL Plasma's donor eligibility policy as it existed on November 17, 2008.

2013, through her attorney, Scott requested her charge be withdrawn and notified the MDHR of her intention to file a civil case. Ex. X. On August 2, 2013, the MDHR acknowledged her withdrawal of the charge. Ex. Y. On September 23, 2013, 4 years and 3 months after filing her charge, 39 months after the finding of probable cause on her amended charge, and 53 days after the MDHR acknowledged withdrawal of her charge, Scott filed the instant lawsuit. Scott alleges in a single count that CSL Plasma violated Minnesota's business discrimination statute, Minn. Stat. §363A.17, on the ground that that CSL Plasma refused to accept a donation of her plasma because of her sexual orientation (transgender). (Compl. ¶¶24-25).

C. Collection of Plasma in the United States.

Plasma is the fluid portion of blood. 21 C.F.R. §640.30.[5] Plasmapheresis "is a procedure in which, during a single visit to the establishment, blood is removed from a donor, the plasma [is] separated from the formed elements, and at least the red blood cells [are] returned to the donor." 21 C.F.R. §640.65(a). Plasma collected by plasmapheresis and intended as source material for further manufacturing use, such as in the manufacture of pharmaceuticals, is referred to as "Source Plasma." 21 C.F.R. §640.60. CSL Plasma collects donated human plasma for manufacture into "biological products that are used in the treatment of diseases" in the United States and around the globe. Ex. C (Simon

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[5] All references are to the *Code of Federal Regulations* (2015) available at the website of the U.S. Government Printing Office, at http://www.gpo.gov/fdsys/browse/collectionCfr.action?collectionCode=CFR.

Tr. 13-14, 173).[6] CSL Plasma is a subsidiary of CSL Behring, a pharmaceutical manufacturer. CSL Plasma collects plasma exclusively for use by CSL Behring. Ex. C (Simon Tr. 171-74). About half of the source plasma for global use in pharmaceutical manufacturing comes from donors in the United States. Ex. L (Simon Article 985).[7]

D. The Concept of Layers of Safety.

1. Redundancy is the key to protection of the plasma supply and patients.

To ensure that the plasma collected at its centers will meet the high standards of safety and quality required for injection into human patients, CSL Plasma adheres to the concept of "layers of safety" or "layers of protection." Ex. C (Simon Tr. 211). Dr. Joseph Kiss, a specialist in blood disorders and Medical Director of Central Blood Bank, and Hemapheresis and Blood Services at the Institute for Transfusion Medicine in Pittsburgh, Pennsylvania, and an Associate Professor Medicine at the University of Pittsburgh, explained this concept in detail. Ex. F (Kiss Report 1); Ex. E (Kiss Tr. 7-9, 30). Dr. Kiss explained that the FDA developed a system to ensure the safety of the blood and plasma supply that employs "layers of safety." Ex. E. (Kiss Tr. 7-9, 30). "Layers of safety" refers to the fact that the FDA cannot rely on any single methodology to keep the blood and plasma supply safe because humans make errors and tests give false-negative results. (*Id.* at 30). The safety of the blood and plasma supply relies on redundancy. (*Id.*). The most important step of that redundancy is donor screening. (*Id.* at 30-37). Before the FDA was able to test blood for HIV, introducing better donor screening, accomplished by excluding high-risk groups from donating blood, reduced the risk of contaminated blood by over 100-fold. (*Id.*). The second step is blood testing. (*Id.*). Neither step achieves perfect results on its own, which is why the FDA relies on both to reduce the risk of contaminated blood to close to zero. (*Id.*).

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[6] The purposes for collection and use of plasma differ markedly from the collection of whole blood, a procedure that is familiar to many Americans. Traditional blood banks accept blood from donors and process it for blood transfusions. Ex. E (Kiss Tr. 9). Whole blood is generally used in the region, or at least in the country, in which it was donated. Ex. D (Simon Report 3). In contrast, plasma is used for a global market and has to meet requirements of pharmaceutical manufacturers in both the U.S. and foreign countries (*Id.*).

[7] It is worth noting that only about 38 percent of the U.S. population is eligible to donate blood and less than 10 percent actually do. American Red Cross, *Blood Facts and Statistics*http://www.redcrossblood.org/learn-about-blood/blood-facts-and-statistics#blood-supply (last visited Aug. 3, 2015).

2. *Studies and Literature Show, and Experts Agree, that Transgender Persons are Far More Likely Than the General Population to Have HIV.*

According to medical literature and scientific studies, transgender individuals have a disproportionately higher risk of contracting HIV than the general population. Ex. E (Kiss Tr. 82). The United States Centers for Disease Control and Prevention ("CDC") reports that in 2009 2.6% of transgender individuals tested newly positive for HIV, compared to 0.9% of non-transgender males and 0.3% of non-transgender females. Ex. N. In other words, transgender individuals are four times more likely to contract HIV than the general population. Ex. G (Iantaffi Tr. 135).

In one mega-study that discussed and synthesized the weighted means of the findings from 29 other studies, 27.7% of male-to-female transgender individuals tested positive for HIV and 11.8% self-reported that they were HIV positive. Ex. E (Kiss Tr. 137); Ex. M (Herbst Article). According to the same mega-study, transgender individuals habitually underestimate their chance of contracting HIV – in one study only 15% of transgender individuals said that they were at greater risk of contracting HIV than most people, contrary to established evidence. Ex. M. The behaviors of transgender individuals and the incidence rate of HIV that results from those behaviors are what make donations from transgender individuals risky to the blood and plasma supply. Ex. E (Kiss Tr. 145).

III. RELEVANT STATUTES, REGULATIONS, AND CSL PLASMA'S POLICIES

A. The Minnesota Business Discrimination Statute.

The sole claim in this case is brought under Minnesota's business discrimination statute. (Compl. ¶¶22-26.) Minn. Stat. §363A.17 provides in relevant part:

> It is an unfair discriminatory practice for a person engaged in a trade or business or in the provision of a service:
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> * * * *
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> (3) to intentionally refuse to do business with, to refuse to contract with, or to discriminate in the basic terms, conditions, or performance of the contract because of a person's race, national origin, color, sex, sexual orientation, or disability, unless the alleged refusal or discrimination is because of a legitimate business purpose.

The statute defines "sexual orientation" to include "having or being perceived as having a self-image or identity not traditionally associated with one's biological maleness or femaleness." Minn. Stat. §363A.03.

To establish a claim under Minn. Stat. §363A.17(3) the plaintiff must demonstrate as a threshold matter that (1) under Minn. Stat. §363A.28, subd. 1 she is "a person aggrieved by a violation of this chapter" and (2) is a party to a contract. *Krueger v.*

Zeman ConsTr. Co., 781 N.W.2d 858, 863-64 (Minn. 2010) ("Only a party to the contract can make the contract or be held legally responsible to 'perform' pursuant to the contract. . . . The legislature did not, however, provide remedies to persons other than the contracting parties, and we cannot add provisions to the statute."); *see also Unity Healthcare, Inc. v. Cnty. of Hennepin*, 2014 WL 6775293 at *9-10 (D. Minn. Dec. 2, 2014). Scott may establish unlawful discrimination under §363A.17 through direct evidence or circumstantial evidence using the prima facie case model of proof set out in *McDonnell Douglas Corporation v. Green*, 411 U.S. 792, 802 (1973); *see also Kalema v. U.S. Oil Co., Inc.*, 2006 WL 2289849 at *2 (D. Minn. Aug. 8, 2006); *Feges v. Perkins Restaurants, Inc.*, 483 N.W.2d 701, 710 (Minn. 1992); and *Sigurdson v. Isanti County*, 386 N.W.2d 715, 719-20 (Minn. 1986). CSL Plasma must be exonerated of any claim of unlawful discrimination if it establishes that its actions were taken "because of a legitimate business purpose."

B. The Federal Regulatory Scheme.

Human blood and blood components, such as plasma, are characterized as "biological products," for purposes of regulation under the federal Public Health Service Act ("PHSA"), as amended, 42 U.S.C. §262(i)(1). Biological products are also subject to regulation under the Federal Food, Drug, and Cosmetic Act ("FDCA"). *See* 21 U.S.C. §321(g).

Under §351(a) of the PHSA, blood and plasma collection centers must be licensed by the Secretary of Health and Human Services ("HHS"). 42 U.S.C. §262(a). Licenses are issued to collection centers only upon a showing that the centers meet certain safety, purity, and potency standards established by the Secretary. 42 U.S.C. §262(d); see also 21 C.F.R. §606.100. HHS is authorized to inspect centers for compliance. 42 U.S.C. §262(c).

The Secretary of HHS has charged the FDA with the responsibility of developing policies to ensure the quality and safety of the blood supply. *See* 21 C.F.R. §5.10(a)(1), 5.10(a)(5) (delegating authority vested in the Secretary of HHS under the FDCA and under §§351 and 352 of the PHSA to the FDA). The FDA has issued federal regulations that establish minimum standards for plasma collected by plasmapheresis; for processing, storing, and labeling plasma units; and for donor eligibility. 21 C.F.R. §§640.60-640.76. Notably, the FDA regulations require that a licensed physician or an individual under a physician's supervision determine the suitability of a particular donor to donate plasma. *See* 21 C.F.R. §640.63(a). Donor suitability determinations are to be based on medical history questions, tests, and a physical examination. 21 C.F.R. §640.63(a); *see also* 21 C.F.R. §640.63(c)(9).

On April 23, 1992 the FDA issued its seminal guidance in a Memorandum from the Director, Center for Biologics Evaluation and Research on the subject of "Revised Recommendations for the Prevention of Human Immunodeficiency Virus (HIV) Transmission by Blood and Blood Products" to All Registered Blood Establishments (the "1992 Blood Memo"). Ex. O ("1992 Blood Memo"). The 1992 Blood Memo identified various groups of high-risk donors who are to be excluded from the donor pool. (*Id.* at 3-5). Among the groups of high-risk donors are individuals with laboratory or clinical evidence of HIV, as well as individuals who are considered to be at an increased risk for

HIV due to activities in which those individuals may have engaged. (*Id.*). For example, subsection I. B. on page 3 of the FDA Recommendations states that any man who has had sex with another man, even once, since 1977 should be deferred from donating blood or blood components (the "MSM policy"). (*Id.*).

The MSM policy was a response by the FDA to initial missteps by blood banks and the FDA itself in response to the early warning signs that AIDS could be, and was being, transmitted through blood transfusions. *See* Ex. P (Fed. Register); Ex. T (Shilts 220-23, 546-47).[8] At a January 4, 1983 meeting of the FDA, The American Red Cross, the American Association of Blood Banks, the National Gay Task Force, and others, scientists argued for screening of blood donors for AIDS. Ex. T (Shilts 220-23). Some advocacy groups resisted these efforts and compared donor screening to miscegenation laws and the internment of Japanese Americans during World War II. (*Id.*). The FDA initially took a middle ground position, stating that there was insufficient scientific evidence to support donor screenings to prevent the transmission of HIV through human blood, a theory that the FDA deemed unproved. (*Id.*). As the HIV/AIDS epidemic continued to rage worldwide and in the U.S. in the late 1970s and the evidence of transmission of HIV through human blood mounted, the FDA began issuing recommendations in 1983 that donors with risk factors for AIDS should be deferred.

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8 The history of the response to the AIDS epidemic in the 1970s and 1980s, and the eventual turnaround by blood banks and the FDA is reported by Randy Shilts in his book, *And the Band Played On (*St. Martin's Griffin 2007). Excerpts are annexed to Willing Declaration as Ex. T.

Ex. T (Shilts 220-23). By that time, hundreds of people had been infected with HIV through blood transfusions. Ex. T (Shilts 546-47).[9]

Since that time, the FDA has continued to study the MSM policy and has met repeatedly with "stakeholders," including representatives of blood banks, plasma collection centers, the medical profession, and members of the public. Ex. P.[10] As a result of these discussions and continuing study, on May 12, 2015, the FDA announced its latest proposed Draft Guidance entitled *Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products: Draft Guidance for Industry* ("Draft Guidance").[11] Ex. Q. Notice of the Draft Guidance and announcement of a 60-day comment period were published on May 15, 2015 in the Federal Register. Ex. P. The Draft Guidance is intended to supersede the FDA's 1992 blood memo when finalized. Ex. P (80 Fed. Reg. at 27974).

Directly relevant to the issue in this case, the Draft Guidance would modify the deferral period for men who have had sex with men from a lifetime deferral to a period of one year. Ex. Q (Draft Guidance at 9-10). Notably, however, with respect to transgender

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9 These points are confirmed in the FDA's May 2015 Draft Guidance, which is discussed in the following paragraph.

10 Specifically, in 2009, an FDA Liaison Meeting discussed transgender donors and that the FDA's position was that a transgender male to female donor should be deferred. Ex. D (Simon Report at 6); Ex. Z (2009 Meeting Minutes).

11 The Draft Guidance was not published in its entirety in the *Federal Register*. The Draft Guidance may be found on the FDA's web site at http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/ucm2008053.htm (last visited July 14, 2015).

donors, the Draft Guidance would continue the FDA's policy of vesting in a collection center's medical director the discretion to determine donor suitability:

> [M]ale or female gender is taken to be self-identified and self-reported. In instances where a donor has asserted a change in gender identification, medical directors may exercise discretion with regard to donor eligibility.

(Draft Guidance at 10).

C. CSL Plasma's Policies.

CSL Plasma is a plasma collection center subject to FDA regulations. 21 C.F.R. §§607.3, 607.07. These regulations impose upon CSL Plasma certain minimum standards and require it to take all reasonable measures to protect the integrity and safety of the plasma donations it accepts. *See* 21 C.F.R. §§640.63, 640.65.

Dr. Toby L. Simon is CSL Plasma's Medical Director and is a principal investigator on clinical research projects, serves on committees relating to medical and scientific issues, and consults on scientific issues for the company. Ex. C (Simon Tr. 10-13). Dr. Simon had a major role in determining CSL Plasma's policies on donor screening. (*Id.* at 23). CSL Plasma's procedures include a Medical Staff Reference Manual ("MSR") that outlines its procedures as they relate to medical decisions. (*Id.* at 39). CSL Plasma strives to ensure that its MSR is consistent with FDA rules and regulations, along with regulations imposed by other countries. (*Id.* at 35-38). The MSR in effect on November 17, 2008 stated that if a potential donor had previously undergone a sex change operation, the CSL Plasma screener should call CSL Plasma's corporate medical operations for direction. (*Id.* at 46-47). Federal regulations require donation centers to defer any potential donor whose identity, including gender, does not match their identification. 21 CFR §640.65(b)(3). For example, the FDA-mandated Donor History Questionnaire ("DHQ") requires CSL to ask all females if they have been pregnant within the last six months and all males if they have had sex with a man anytime since 1977. (*Id.* at 56-60).[12]

IV. ARGUMENT

A. The Applicable Legal Standard for Summary Judgment.

Defendant is entitled to summary judgment if, when the evidence is viewed in the light most favorable to Plaintiff, there are no genuine issues of material fact and Defendant is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c). Once Defendant meets its initial burden of presenting this Court with a basis for its motion and identifying those portions of the record that demonstrate the absence of a genuine issue of material fact, Plaintiff bears the burden of setting forth specific facts showing that there is sufficient evidence in her favor to allow a jury to return a verdict for her. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323-24 (1986). Plaintiff, as the nonmoving party, may not rest upon mere denials or allegations in the pleadings. Fed. R. Civ. P. 56(e)(2). A failure of proof regarding any essential element of Plaintiff's claims on which she bears the burden of proof renders all other facts immaterial. *Celotex*, 477 U.S. at 322-23. "Summary

[12] The Donor History Questionnaire ("DHQ") is a set of questions designed by medical professionals, blood bank and plasma collection center medical directors and staff, and which is reviewed and approved by FDA and its advisory groups. The DHQ in various forms has been used in the U.S. for more than 60 years. See http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/ucm2008053.htm (last visited Jul 14, 2015).

judgment is particularly appropriate when the disputed issues are primarily legal rather than factual." *Select Comfort Corp. v. Arrowood IndEx. Co.*, 2014 WL 4232334 at *4 (D. Minn. Aug. 26, 2014) (citing *Schrier v. Halford*, 60 F.3d 1309, 1310 (8th Cir. 1995)).

B. This Suit is Untimely under Minnesota Law and Should be Dismissed.

The Minnesota Human Rights Act provides that an aggrieved person may file a charge with the MDHR or proceed directly to court. Minn. Stat. §§363A.28, subd. 1, 363A.33, subd. 1. A charge or a suit is timely if filed within one year of the alleged discriminatory event. Minn. Stat. §363A.28, subd. 3. It appears that Scott's original charge filed with the MDHR on April 20, 2009 was timely. She filed an amended charge on October 23, 2009. Exs. U & V.

The case languished in the MDHR for more than four years before those proceedings were terminated. This delay was not the result of any action by CSL Plasma. On June 25, 2010, the MDHR issued a finding of probable cause on Scott's amended charge, alleging "business discrimination" under Minn. Stat. §363A.17. Approximately 4 years and 3 months after she filed her original charge, on July 31, 2013, Scott's counsel requested withdrawal of the charge and notified the MDHR of Scott's intent to sue in court.[13]

The statute provides that, following receipt of notice of dismissal of a charge or a finding of no probable cause, an aggrieved person may file suit in court within 45 days.

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[13] In her First Amended Complaint, Scott avers that she requested a Notice of Right to Sue. Compl. ¶19. This appears not to be case. Instead, she requested withdrawal of her charge, and the MDHR subsequently acknowledged withdrawal of the charge.

Minn. Stat. §363A.33, subd. 1(1)(3).[14] The statute does not address expressly when a person may file a civil suit after a finding of probable cause is made, but it does speak to the deadline to file suit when more than 45 days has passed from the filing of a charge and neither a hearing has been held nor a conciliated agreement has been entered into. In such case, the charging party may give notice to the MDHR of her intent to file suit and then must file suit within 90 days thereafter. Minn. Stat. §363A.33, subd. 1(3). Apparently, it is this provision of the statute upon which Scott relies for her contention that her suit is timely because it was filed within "the 90-day limitations period of the Minnesota Human Rights Act." Compl. ¶20.

This scenario is nearly identical to that presented in *Powers-Potter v. Nash Finch Co.*, 2014 WL 2003063 at *2 (D. Minn. May 14, 2014). In that case, as here, the plaintiff dual-filed a timely charge with the MDHR and EEOC. The EEOC investigated the charge and issued a probable cause finding more than four years later. Recognizing the Minnesota Supreme Court's holding in *State by Beaulieu v. RSJ, Inc.*, 552 N.W.2d 695 (Minn. 1996) that a delay by MDHR of 31 months in issuing a decision is *per se* prejudicial, the district court dismissed the state claims. The plaintiff attempted to salvage her state law claims by relying on §363A.33, subd. 1(3). The district court rejected her argument, holding that while she "has literally complied with the requirements of §363A.33, subd 1(3). . . . that statute cannot be read to permit a party to notify the Department of an intent to file a lawsuit more than four years after filing an administrative charge" lest the Minnesota Supreme Court's holding in *Beaulieu* be eviscerated. *Powers-Potter*, 2014 WL 2003063 at *2.

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[14] Notice is presumed to have been received five days after service by mail of the notice. Minn. Stat. §363A.33, subd. 1.

In this case, Scott waited more than four years to file her suit, as long as the four-year delay in *Powers-Potter* that required dismissal and a year longer than the 31-month delay in *Beaulieu* that required dismissal as a matter of law. Dismissal of Scott's Complaint is mandated by the Minnesota Supreme Court's decision in *Beaulieu.*

C. The Court Should Grant Summary Judgment Because This Claim Does Not Fall Within the Scope of Minn. Stat. §363A.17.

Donating plasma is not a business transaction and is not covered by Minn. Stat. §363A.17. When a person presents herself at CSL Plasma, she is offering to *donate* plasma for use in pharmaceuticals. She is not *selling* plasma, as the sale of blood or plasma by an individual is illegal in the United States. *See* 42 U.S.C. §274e. Instead, The Minnesota Legislature has declared that donations of blood or blood components represent the rendition of a health care service by each party to the other and "is not a sale of goods" or a "sale of a product" for purposes of Article 2 of Minnesota's Uniform Commercial Code. Minn. Stat. §525A.25.[15] Although §525A.25 was enacted to address a different situation, the Legislative intent to remove donations of blood and blood components (plasma) from the realm of a commercial transaction cannot be discounted when determining whether a person's offer to donate plasma, which offer is declined by the plasma collection center, constitutes the denial or infringement of a legal right. Construing Minn. Stat. §§363A.17 and 363A.28, subd. 1. The Minnesota Supreme Court has held that "a person is 'aggrieved' in the legal sense when she has suffered the denial or infringement of a legal right." *Krueger v. Zeman Const. Co.*, 781 N.W.2d 858, 862 (Minn. 2010).

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[15] As this Court has observed previously, this statute is commonly referred to as the "blood shield law." Its purpose is to prevent products liability suits against blood banks, plasma collection center, and against donors, in the event of infection of a recipient of the blood or plasma contracts a communicable disease. See *Balkowitsch v. Minneapolis War Memorial Blood Bank, Inc.,* 132 N.W.2d 805, 810 (Minn. 1965).

The requirement of infringement of a legal right is an essential limitation on the scope of §363A.17, for otherwise the statute would be unbounded. Under Minnesota law, no one has a *legal right* to donate blood or plasma. No blood or plasma collection center is under a legal obligation to accept all proffered donations of blood or plasma. Whether a person's offer to donate plasma will be accepted by a licensed collection center such as CSL Plasma depends on various factors, including supply and demand at that time; the health condition of the donor; the eligibility of the donor under the regulations promulgated by the FDA, and the collection centers' medical professionals' judgment. Unlike the situation where a transgender person seeks to purchase a wedding cake or flowers or a scarf at a retail store, there is no offer by the plasma collection center to sell any product or service to the potential donor. Thus, as in *Krueger*, this claim fails because the Plaintiff cannot show that she is "aggrieved" within the meaning of the MHRA.

D. The Court Should Grant Summary Judgment Because the Minnesota Statute Requires the Existence of an Enforceable Contract,

The Minnesota Supreme Court has held that Minn. Stat. §363A.17(3) "does not provide a cause of action for a person not a party to a contract, the performance of which is affected by business discrimination." *Krueger*, 781 N.W.2d at 863. "Only a party to the contract can make the contract or be held legally responsible to "perform" pursuant to the contract." *Id.* at 864. "The legislature did not, however, provide remedies to persons other than the contracting parties, and we cannot add provisions to the statute." *Id.*

It is not enough that a person desires to enter into a contract. As this Court observed recently, the Minnesota Supreme Court in *Krueger* did "not distinguish [the failure to do business] clause from the statute's other clauses when it state[d] that section 363A.17 'does not provide a cause of action for a person not a party to a contract.'" *Unity Healthcare, Inc. v. Cnty. of Hennepin*, 2014 WL 6775293 at *10 (D. Minn. Dec. 2, 2014) (quoting *Graphic Commc'ns Local 1B Health & Welfare Fund "A" v. CVS Caremark Corp.*, 850 N.W.2d 682, 689-90 (Minn. 2014)).

Scott does not allege in her Complaint that she is or was a party to a contract with CSL Plasma. Scott's actions can be viewed at most as an offer to create a unilateral contract that could have become a contract only by performance by CSL Plasma, i.e., accepting the plasma donation. Under Minnesota contract law, "[w]hen a promise is thus accepted by performance of the designated act or forbearance, the promisor's offer is converted into a unilateral contract which comes into being the moment the act or forbearance has been fully performed." *Hartung v. Billmeier*, 66 N.W.2d 784, 789 (1954). Assuming, *arguendo,* this interaction to be contractual in nature,[16] no contract could have been formed until CSL Plasma accepted the plasma donation. Indeed, at any point in time until the completion of the plasma donation process, the donor can revoke

[16] CSL Plasma does not concede that the interaction of a potential donor and donee of plasma is a contractual relationship.

his or her offer without repercussions. All potential donors are offered a final, private opportunity to self-exclude and terminate the process. Ex. B (Erickson Tr. 71-72) Ex. H (Performing a Health Assessment at 15). If Scott had reached the end of her screening, she would have been given one last chance to walk away from the process, no strings attached, before donating her plasma. Furthermore, a potential donor is not eligible to enter into a "contract" to donate until she passes all of the pre-screening protocols and is deemed healthy and otherwise eligible to donate. Therefore, no contract was created between Scott and CSL Plasma on November 17, 2008. In the absence of a valid and binding contract, Scott cannot bring a claim under the business discrimination statute and CSL Plasma is entitled to judgment as a matter of law.

E. The Court Should Grant Summary Judgment Because Defendant had a Legitimate Business Purpose for Not Accepting Plaintiff's Plasma Donation.

Even if Minn. Stat. §363A.17 applied to the donation of plasma, CSL Plasma is entitled to judgment as a matter of law because it has demonstrated on this record that its deferral of Scott on November 17, 2008 was based on a legitimate business purpose. CSL Plasma must ensure the safety of its plasma to protect the health and safety of the thousands of patients worldwide that rely on the plasma-based pharmaceuticals to survive. As a licensed and regulated plasma collection center, CSL Plasma must follow FDA regulations and guidance, and its medical directors must use their own professional judgment to determine whether a prospective donor may *safely* make a donation – with due regard for the health of the donor and for the ultimate user of the plasma products to be injected into patients. 21 C.F.R. §640.63(a).

In this case, CSL Plasma's Medical Director and its outside expert witness[17] have articulated legitimate business purposes for the deferral of Scott on November 17, 2008. In his expert report, Dr. Joseph Kiss stated:

- "Although it is commonly assumed that risk factors for viral disease, e.g., HIV, are not important in determining the inherent risk of a particular donor population because 'all blood is tested,' exclusion of high risk donors, in fact, has played an essential role in maintaining blood and plasma safety." Ex. F (Kiss Report at 4).
- "[T]he screening procedures in place that preclude high risk donors from donating reduce the risk of a positive unit being drawn, by at least 120-fold." (*Id.*).
- "Deferral of defined groups at risk for HIV reduces the 'net' or residual contamination rate of the blood that is collected by preventing entry into the blood and plasma supply of 1) units having a false negative results (as occurs during the early 'window period' between the time of infection and the time the test becomes positive), 2) units from donors who may harbor new viral strains or variants that are not detected by the established test, or 3)

[17] Dr. Joseph Kiss is a retained expert witness who has been so designated under Fed. R. Civ. P. 26(a)(2). Dr. Toby L. Simon is both a fact witness, because he was CSL Plasma's Medical Director in 2008 and is now CSL Behring's Senior Medical Director, Plasma and Plasma Safety in Plasma Product Development, and has been identified under Fed. R. Civ. P. 26 (a)(2). Both Drs. Kiss and Simon prepared written reports, which are cited in this Memorandum and annexed to the Willing Declaration as Exs. F and D, respectively.

contaminated products that are inadvertently released form inventory through error (e.g., mislabeled or misidentified units).” (*Id.* at 5).

- “Even though the testing measures are highly effective, there is still a chance that HIV-infected blood could make it through, such that the layers of safety (including deferral of high risk donors to ensure the safest possible donor base) remain necessary.” (*Id.* at 5).
- “FDA has maintained that having multiple layers strengthens the safety ‘net’ because it protects against a breach due to failure of any one measure.” (*Id.* at 5).
- “As the FDA has repeatedly stated, donor eligibility decisions regarding transgender individuals should be based on risk.” (*Id.* at 6).
- “In summary, these studies provide documentation that female transgender individuals have higher rates of HIV positivity and risk behaviors than MSM. MSM continue to be deferred indefinitely from blood and plasma donations. Even if they are HIV negative at the time of prospective donation, female transgender individuals remain at high risk of HIV because of increased risk behaviors, even higher than those reported in MSM. It is my opinion, therefore, that the proportionate increased risk associated with female transgender individuals as a group represents a compelling rationale for deferral from blood and plasma donation and justifies this policy.” (*Id.* at 8).

Dr. Kiss was deposed on June 9, 2015, and testified further that:

- "I think there is a degree of risk in the transgender population that goes beyond MSM risk. I think that we – and furthermore, I don't think we truly understand the level of that risk, when it occurs, what groups in particular that risk resides in, and which groups for that matter may be safer than others. I don't think we really understand that." Ex. E (Kiss Tr. 160).
- "So I think this is an area that is developing as society changes, and the view, I think it is more on the radar screen to look at. I don't think it has been addressed appropriately, and I think it's analogous to the situation, you know, 20, 30 years ago with MSM. We studied it, it's been now characterized, I think those behaviors, those interpretations of gender, also what goes with that is the questioning. The way that the questions are addressed in that population. I think those all need to be – first of all, where is the risk? It may not be in the entire population, but I think the safest thing now is to assume a precautionary principle in that we have to create – treat that group, because it is an unknown. So I think we have to develop the science, the science should inform the decisions. I think we have to develop the screening procedures. And I think that they are a special group right now. Like it or not, this is something we are dealing with, and we have to treat them as such." Ex. E (Kiss Tr. 160-61).

According to Dr. Kiss, there is a "strong medical and scientific basis at the present time" to exclude transgender individuals from donating blood and plasma. Ex. E (Kiss Tr. 7-9, 16). The risk of a transgender individual being HIV positive is "quite high," higher or at least as high as for men who have sex with men. (*Id.* at 83). Without better data, it is premature to accept donations from transgender individuals. (*Id.* at 150). There are additional behaviors and risk factors in the transgender population that are not captured in the current screening process. (*Id.* at 187). The safety of the blood and plasma supply relies on the redundancy of donor screening and blood and plasma testing. (*Id.* at 30-36). Neither step achieves perfect results on its own, which is why the FDA relies on both to reduce the risk of contaminated blood to close to zero. (*Id.* at 31-37). The safest stance currently is to defer all transgender individuals as a precautionary measure until more studies are done and better screening processes are developed. (*Id.* at 161).

Notably, Plaintiff's designated expert witness, Dr. Alex Iantaffi,[18] who holds a Ph.D. in Disability, Gender Studies, Higher Education, Community Health, Women's Health, agrees that we "definitely need more evidence" on the risk of HIV in transgender populations and that "[t]here are limitations in terms of the knowledge that we currently hold in the field." Ex. G (Iantaffi Tr. 57). Dr. Iantaffi admits that the current research from the CDC shows that the rate of HIV in transgender individuals is substantially higher than in the general population, about four times higher. Ex. G (Iantaffi Tr. 134-35); Ex. N (CDC Report). When asked if he could cite to any articles or studies or data that supported his position that transgender persons should be allowed to donate plasma, Dr. Iantaffi said: "I believe that the literature doesn't exist, that this has not been tackled yet in terms of scholarship." Ex. G (Iantaffi Tr. 104). When asked if he had any data to support his opinion that the plasma donation centers are discriminating against transgender individuals, he replied: "Not specifically about plasma centers per se. That has not been my area of focus in terms of research." Ex. G (Iantaffi Tr. 142).

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[18] Defendant does not concede hereby that Dr. Iantaffi is qualified to testify as an expert at trial and reserves the right to file a *Daubert* motion at the appropriate time.

Dr. Toby L. Simon, CSL Plasma's Medical Director, and the physician who concluded that a blanket deferral of transgender potential donors was the most prudent and safe procedure to follow, gave his reasons in support of the policy:

- "The FDA regulates Source Plasma donor centers to assure that the procedure is safe for the donors and that the product is safe for patients." Ex. D (Simon Report at 5).
- "The FDA Recommendations identify various groups of 'High-risk' donors who are to be excluded from the donor pool." (*Id.* at 5).
- "In my experience working in the blood services industry, transgender donors present a challenge to the donor center in performing a donor suitability evaluation in keeping with the MSM rule. First, there are separate questions for males and females. The center must determine which questionnaire to use for the individual. Second, some individuals have changed their sex since an earlier donation. The electronic record system used by donor centers do not allow for a change in gender. Third, the center must determine if the transgender situation is one in which there has been MSM deferring the donor. For example, if a person born male changes later in life to female and has

heterosexual relations as a female with males, does the MSM rule apply?" (*Id.* at 6).[19]

- "In light of these issues, CSL's corporate medical staff determined that we would establish a policy to ensure the safety of the product by implementing a protocol that I believe more effectively implements the FDA's guidance and mandates to protect the integrity of the plasma supply." (*Id.* at 7).
- "Our company seeks more Source Plasma donors. However, there is no 'right to donate.' There is a right for the patients we serve to get the most efficacious and safest product we can reasonably provide. Thus, we must err on the side of safety." (*Id.* at 7).
- "FDA will require epidemiological evidence and sound scientific data related to disease transmission before it changes its policy." (*Id.* at 7).

Dr. Simon was deposed on June 10, 2015 and further testified that:

- "I think it is very difficult for our staff to be able to deal with all the possible scenarios and try to construct a different solution in each case, and that my concern is that an error will be made, and a unit will be accepted and that should not be, and/or that there will be a regulatory issue that will result from such an ad hoc decision." Ex. C (Simon Tr. 205).

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[19] Likewise, if a person born male changes later in life to female and classifies herself as a lesbian, how does the center determine if the MSM rule applies for the years the person spent as a male?

- "I just find it very complex and difficult, particularly with all of the variations of transgender in the way people identify themselves. I think it would be difficult to develop consistent questions and validate them, and ensure that they meet our requirements for safety." (*Id.* at 209-10).
- When asked about asking transgender donors different questions, he replied that "I think it creates a complexity that we are not anxious to have. And we feel – I feel that – my professional judgment, that it would not add to the safety of the blood supply, and could possibly compromise it." (*Id.* at 210).
- "And, you know, we put a, you know, fence around the safety rules to try to achieve a safety level, and this is one of the layers of protection that we've chosen to establish. I mean, there are always instances that probably one could bring up with any of the restrictions that we have, but they are either proven to work, or they are based on good epidemiologic data, or they have been validated in use, or whatever reason we believe that they create a margin of safety that we wish to continue." (*Id.* at 211-12).

On the issue of patient safety, Plaintiff's expert, Dr. Iantaffi, agrees with CSL Plasma's expert witnesses that "blood and plasma safety is paramount. I just want to make that clear. And on a personal note, I have been the recipient of blood transfusions, so I'm very aware of the importance of blood safety and plasma safety." Ex. G (Iantaffi Tr. 86).

All of the expert witnesses agree that the current medical-scientific research shows that transgender individuals have a much higher rate of HIV than the general population.

Therefore, in line with the best medical information currently available, CSL Plasma must take a conservative approach. That undisputed increased risk alone gives CSL Plasma a legitimate business reason to protect the integrity of its plasma supply by screening out individuals who studies have shown have a high risk of contracting HIV, such as transgender individuals.

Dr. Simon also testified that if a plasma donation center does not defer high-risk individuals it risks being shut down. For example, if the rate of hepatitis and HIV of the plasma center's donors is too high, the center can no longer provide its plasma to a pharmaceutical company and must close. Ex. C (Simon Tr. 158-61). Indeed, Dr. Simon testified that CSL Plasma shut down a center in West Virginia in 2008 because of an elevated viral marker rate for Hepatitis C (*Id.* at 213-14). Therefore, donors who are at a higher risk of developing HIV or hepatitis are deferred. (*Id.* at 159). Adhering to federal rules and guidelines and avoiding regulatory sanctions are legitimate business purposes for CSL Plasma's decision to defer Scott.

F. The Court Should Grant Summary Judgment to CSL Plasma Because the Object of this Litigation is a Matter for the FDA.[20]

The Food and Drug Administration ("FDA") has been charged by Congress with the responsibility of regulating blood and plasma collection in the United States, including setting the standards for donor eligibility. This important medical and scientific matter, which significantly implicates public health, has been committed to a federal administrative agency, which has used its expertise and experience to promulgate regulations and issue guidance regarding the safe collection of blood and plasma. CSL Plasma follows those regulations and the guidance of the FDA, which licenses its centers.

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[20] The issues of primary jurisdiction of the FDA and federal preemption were raised in Defendant's Motion for Judgment on the Pleadings (ECF No. 20). They are raised again here because (1) CSL Plasma does not intend to waive the issue and desires to preserve them for any appeal that may follow, and (2) recent actions taken by the FDA in May 2015 demonstrate that the issue of the MSM Rule and its application to transgender persons is under active consideration by the federal agency.

In this case, Scott asks the Court to substitute its judgment for that of the FDA and medical professionals to whom the agency has delegated the authority to determine who can safely donate blood or plasma. Scott, essentially, asks this Court to overrule policies and procedures that have been in place for decades and which are the subject of an active, ongoing review by the FDA. Although the FDA has not always been explicit in expressing its views concerning donations of blood or plasma by transgender individuals, in May 2015, the FDA announced its latest proposed Guidance on the subject of donor eligibility of persons whose gender identity does not match their birth gender in which it specifically delegated to the medical personnel of the collection centers under its jurisdiction the determination of eligibility to donate of transgender persons. There is no question that the actions taken by CSL Plasma concerning Scott in 2008, and its position today, are in accord with FDA regulations and policies. Nor, in light of the FDA's May 2015 Draft Guidance, should there now be any doubt that the issue presented in this case is one that is under active consideration by the FDA and that it is a matter for the FDA to decide in the first instance.

1. *The Eligibility Criteria for the Donation of Plasma is Within the Primary Jurisdiction of the Food and Drug Administration.*

The primary jurisdiction doctrine governs "the proper relationships between the courts and administrative agencies charged with particular regulatory duties." *United States v. W. Pac. R.R. Co.*, 352 U.S. 59, 63 (1956). The doctrine permits dismissal or a stay of a lawsuit when adjudication of a claim "requires the resolution of issues which, under a regulatory scheme, have been placed within the special competence of an administrative body." *Id.* at 63-64.

Two rationales underlie the doctrine. First, "courts apply the doctrine of primary jurisdiction . . . to obtain the benefit of an agency's expertise and experience." *Access Telecomms. v. Sw. Bell Tel. Co.*, 137 F.3d 605, 608 (8th Cir. 1998). Thus, referral of a matter to a relevant administrative body is appropriate when a case "rais[es] issues of fact not within the conventional experience of judges" or "requir[es] the exercise of administrative discretion." *Id.* (quotation marks omitted).

Second, courts defer to agencies "to promote uniformity and consistency within the particular field of regulation." *Id.* There is no set test or formula for determining whether deferral to an agency under the primary jurisdiction doctrine is warranted. *Id.* Rather, each case must be examined to determine whether the rationales for the doctrine are present and whether applying the doctrine will aid the purposes for which it was created. *Id.*

The FDA's decades of experience regulating blood and plasma collection provide it with specialized expertise and experience. The FDA has been charged with the responsibility of developing policies to ensure the quality and safety of the blood supply. In line with that responsibility, the FDA has promulgated regulations setting minimum standards for donor eligibility, the collection of plasma, and for processing, storing, and labeling plasma units. 21 C.F.R. §§640.60-640.76.

In a recent case involving another highly-regulated industry, the Eighth Circuit held, under the primary jurisdiction doctrine, that the Surface Transportation Board ("STB") was better positioned than the court to rule on whether the Soo Line Rail Road could impose reasonable requirements beyond the minimum regulations. *Chlorine Inst., Inc. v. Soo Line R.R.*, 2015 WL 4032056, at *5 (8th Cir. July 2, 2015). According to the court, the STB was in a better position to determine which requirements were reasonable because it is a "complex, fact-intensive inquiry that requires knowledge and consideration of the industry at issue." *Id.* The Court of Appeals' reasoning in this case applies with equal force to the FDA's regulation of blood and plasma collection centers. To protect the blood and plasma supply, the FDA has issued detailed risk-based recommendations addressing donor eligibility and outlining groups of people who should be deferred from donating blood or plasma. Ex. O (1992 Blood Memo). The FDA's Guidance was based on years of study, consultation with medical professionals and other stakeholders, and represents the agency's considered judgment of how best to protect the blood and plasma supply and those individuals who depend on the medicines derived from plasma.

Scott seeks to hold CSL Plasma liable for declining to accept a donation of plasma from her. Fundamentally, Scott seeks to challenge the appropriateness of CSL Plasma's donor eligibility decision through a human rights statute. But this she cannot be permitted to do. The appropriateness of a donor eligibility decision is squarely a matter for the FDA—the agency responsible for setting donor eligibility standards.

Similarly to the railroad industry, the plasma donation industry is complex and any changes to the procedures set out in federal regulations involve a complex and fact-intensive inquiry based on current scientific research and the knowledge of the industry. Although Scott may believe that one or more of the FDA's current policies are discriminatory and in need of revision, this is precisely the type of decision that Congress committed, in the first instance, to the expertise of an administrative agency. The FDA is better equipped, through its decades of expertise and experience, to consider and make changes to donor eligibility and deferral policies.

Scott's expert agrees that "blood safety and plasma safety is paramount" and that "the FDA has the best intention around protecting transfusion recipients" and other patients. Ex. G (Iantaffi Tr. 83, 86). He further stated that the FDA has the ultimate authority to update its screening procedures, (*id.* at 98), and that the FDA's screening procedures should be designed to screen out anyone whose plasma might pose a risk to a patient, (*id.* at 128), taking this dispute out of the realm of judicial determination. Ultimately, as Scott's expert concedes, this is a matter for the FDA. (*Id.* at 160).

Moreover, dismissal under the primary jurisdiction doctrine is particularly appropriate where a claim involves an ongoing public health issue. *See Gordon v. Church & Dwight Co.*, No. C 09–5585 PJH, 2010 WL 1341184, at *1-*2 (N.D. Cal. Apr. 2, 2010). The FDA has promulgated regulations and guidance addressing donor eligibility and the exclusion of certain high risk donors in order to protect the public health.

Specifically, the regulations and guidance are meant to prevent contamination of blood and plasma products with communicable diseases and protect the safety and integrity of the blood supply (and the products manufactured therefrom).

The FDA's continued review of donor eligibility issues and, specifically, deferrals of certain high risk groups, demonstrates that such matters are an ongoing public health issue. Although Scott's claim is couched in terms of a state human rights statute, her claim implicates this ongoing public health concern. Accordingly, at this juncture, it is an issue for the FDA, not the courts.

2. Deferring this Matter to the FDA Promotes Uniformity and Consistency within the Field of Regulation of Plasma Collection.

Scott seeks a determination that CSL Plasma violated Minn. Stat. §363A.17 when it declined a plasma donation from her on the basis of her sexual orientation (transgender). A finding for Scott in this case would be tantamount to a finding that CSL Plasma must accept donors based on their protected status as opposed to policies based on accepted scientific findings. CSL Plasma is, however, obligated to comply with the current federal regulatory scheme addressing donor eligibility and deferral decisions.

It is also the FDA's position that plasma donation centers ask gender-specific questions of every donor, both for the safety of the donor and the safety of the plasma supply. For example, females are asked about recent pregnancies, because donating plasma might be harmful to a woman who was recently pregnant. Alternatively, males are asked about recent sex with males, for the safety of the plasma supply. The FDA does not allow for any deviations from its DHQ without the center going through an approval process. Ex. R (2006 DHQ Guidance); Ex. S (2013 DHQ Guidance).

Attempting to regulate plasma and blood donor eligibility policies by judicial fiat would lead to inconsistent results around the country because such policies are based on existing expert, scientific, and medical data. They are, by their nature, risk-based decisions. While one court may interpret the current state of scientific and medical data to support a change to an existing donor deferral policy, another court may find that the current data does not support a change. The FDA, on the other hand, is one agency, and it has the ability—and congressionally sanctioned responsibility—to regulate donor eligibility decisions uniformly and consistently throughout the states.

Through its expertise, experience, and flexible rule-making procedures, the FDA is better suited than the courts to address issues relating to donor eligibility decisions. The FDA and its advisory groups hold meetings and solicit comments so that a uniform standard, based on current scientific research, can be applied to all regulated companies. Scott is free to submit comments and present contrary evidence to the FDA if she disagrees with its proposed guidance.

Because this Court cannot give Scott the relief she seeks without articulating a position that is inconsistent with current FDA policies, the Court should defer to the FDA so that it may continue to review its donor eligibility policies, as it has done constantly for more than a decade and continues to do to this day.

3. *The Inherent Conflict that Attempts to Comply with Both the State Statute and Federal Law Impose on CSL Plasma Support a Finding that Use of the Minnesota Human Rights to Determine Who May Donate Plasma is Preempted by Federal Law.*

A state law that conflicts with federal law is preempted under the Supremacy Clause of the U.S. Constitution. U.S. Const. art VI, cl. 2. Conflict preemption arises when state law actually conflicts with federal law and (1) it is impossible for a private party to comply with both federal and state regulations ("impossibility preemption") or (2) when state law stands as an obstacle to the accomplishment and execution of the purposes and objectives of Congress ("obstacle preemption"). *Geier v. Am. Honda Motor Co., Inc.*, 529 U.S. 861, 899, (2000). State laws may be preempted by both federal statutes and federal regulations. *Hillsborough County, Fla. v. Automated Med. Labs.*, Inc., 471 U.S. 707, 712-713 (1985) (citing cases); *see also Fidelity Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 153 (1982) ("Federal regulations have no less preemptive effect than federal statutes.").

In this case, Scott seeks a determination that CSL Plasma violated the Minnesota business discrimination statute by declining a donation of plasma from her because of her sexual orientation (transgender). Such a finding would amount to a judicial pronouncement that CSL Plasma is required to accept donors without regard to their sexual orientation.

Such a finding would also stand in the way of the federal goal of protecting the safety and integrity of the nation's blood supply. It is indisputable that the FDA has been charged with the responsibility for developing policies to ensure the quality and safety of the nation's blood supply. In furtherance of that overarching goal, and in line with the authority delegated to it by HHS, the FDA has established minimum standards for conducting plasmapheresis; for processing, storing and labeling plasma units; and for determining *donor eligibility*. *See* 21 C.F.R. §§640.60-640.76.

In sum, granting Scott the relief she seeks would have the effect of making it impossible for CSL Plasma to comply with its obligations under both state and federal law and would create a serious obstacle to the FDA's goal of protecting the safety and integrity of the nation's blood and plasma supply. Accordingly, her claim under Minn. Stat. §363A.17 is preempted by federal law.

V. CONCLUSION

As a threshold matter, this suit was not timely filed and requires dismissal. Even if the Court were to reach the merits of this case, Plaintiff cannot establish that she was a party to a contract with CSL Plasma to donate plasma. The donation of plasma, moreover, is a not commercial or business transaction within the ambit of Minn. Stat. §363A.17. Moreover, even if the donation of plasma were within the ambit of the statute, CSL Plasma has stated legitimate business purposes for deferring transgender donors, including protecting the safety of the blood supply and staying in business. Because of those legitimate business purposes, CSL Plasma is entitled to judgment as a matter of law.

Finally, the determination of donor eligibility is a matter within the primary jurisdiction of the FDA. The Minnesota Human Rights Act's Business Discrimination provision cannot be employed as an indirect method of state regulation of donor eligibility and, if applied as sought by Plaintiff, would create an irreconcilable conflict between state and federal laws and regulations that would make it impossible for CSL Plasma or any blood bank or plasma collection center to comply with both sets of laws.

For the foregoing reasons, and based on the entire record in this case, Defendant respectfully requests that its Motion for Summary Judgment be granted in its entirety, and that this Court enter an Order dismissing Plaintiff's First Amended Complaint in its entirety, with prejudice.

Dated: August 14, 2015

Respectfully submitted,

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